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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION IX

REGISTRAR
REGIONAL HEARING CLERK

In the Matter of:

VF OUTDOOR, INC.,

Respondent.

Docket No. FIFRA-09-2009-0019

**ANSWER TO COMPLAINT AND NOTICE OF OPPORTUNITY FOR HEARING,
AFFIRMATIVE DEFENSES, AND REQUEST FOR HEARING**

Respondent VF Outdoor, Inc. (hereinafter, "Respondent"), by and through its undersigned counsel, pursuant to 40 C.F.R. § 22.15, answers the Complaint and Notice of Opportunity for Hearing (hereinafter, "Complaint") filed by the Associate Director for Agriculture, Communities and Ecosystems Division, United States Environmental Protection Agency, Region 9 (hereinafter, "Complainant") as follows.

GENERAL DENIAL

Unless specifically admitted below, Respondent denies each and every allegation contained in the Complaint, including Complainant's proposed civil penalty.

RESPONSE TO SPECIFIC ALLEGATIONS

The following numbered responses correspond to the numbered paragraphs set forth in Complainant's Complaint:

1. Respondent denies that it is a California corporation. The remaining allegations contained in numbered paragraph one (1) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent admits that it is a "person" within the meaning of section 2(s) of the Federal

Insecticide, Fungicide, and Rodenticide Act (hereinafter, "FIFRA"), 7 U.S.C. § 136(s), but Respondent denies that it is subject to FIFRA or any implementing regulation promulgated thereunder as regards the sale or distribution of any "shoe product" identified in the Complaint (hereinafter, "Shoe Product").

2. Respondent denies that it manufactures apparel, shoes, or sporting goods under the trade name "The North Face." Respondent admits that it sells and distributes apparel, shoes, and sporting goods under the trade name "The North Face."

3. Numbered paragraph three (3) of the Complaint contains arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph three (3) of the Complaint.

4. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph four (4) of the Complaint and, therefore, denies the same.

5. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph five (5) of the Complaint and, therefore, denies the same.

6. Respondent denies the allegations contained in numbered paragraph six (6) of the Complaint.

7. The allegations contained in numbered paragraph seven (7) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph seven (7) of the Complaint.

8. The allegations contained in numbered paragraph eight (8) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies that bacteria “on or in living man” are “pests” under 40 C.F.R. § 152.5(d).

9. The allegations contained in numbered paragraph nine (9) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies that any Shoe Product is a “pesticide” within the meaning of, or for any purpose under, FIFRA or the United States Environmental Protection Agency’s (hereinafter, “EPA’s” or “the Agency’s”) implementing regulations.

10. Respondent admits that no Shoe Product was registered under FIFRA § 3, 7 U.S.C. § 136a, at any time relevant to this action, but Respondent denies Complainant’s implicit legal conclusion that the Shoe Products are “pesticides” within the meaning of, and for all purposes under, FIFRA and EPA’s implementing regulations and, therefore, require registration under FIFRA § 3, 7 U.S.C. § 136a. Rather, Respondent alleges that the Shoe Products contain a “pesticide,” namely, Agion Silver Antimicrobial Type AJ, EPA Reg. No. 71227-1-72854 (hereinafter, “Agion Type AJ”), to protect the footbeds of the Shoe Products against bacteria, and Agion Type AJ was registered under FIFRA § 3, 7 U.S.C. § 136a, at all times relevant to this action.

11. The allegations contained in numbered paragraph eleven (11) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph eleven (11) of the Complaint.

12. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

13. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph thirteen (13) of the Complaint and, therefore, denies the same.

14. The allegations contained in numbered paragraph fourteen (14) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph fourteen (14) of the Complaint.

15. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

16. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph sixteen (16) of the Complaint and, therefore, denies the same.

17. The allegations contained in numbered paragraph seventeen (17) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph seventeen (17) of the Complaint.

18. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

19. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph nineteen (19) of the Complaint and, therefore, denies the same.

20. The allegations contained in numbered paragraph twenty (20) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph twenty (20) of the Complaint.

21. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

22. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph twenty-two (22) of the Complaint and, therefore, denies the same.

23. The allegations contained in numbered paragraph twenty-three (23) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph twenty-three (23) of the Complaint.

24. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

25. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph twenty-five (25) of the Complaint and, therefore, denies the same.

26. The allegations contained in numbered paragraph twenty-six (26) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph twenty-six (26) of the Complaint.

27. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

28. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph twenty-eight (28) of the Complaint and, therefore, denies the same.

29. The allegations contained in numbered paragraph twenty-nine (29) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph twenty-nine (29) of the Complaint.

30. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

31. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph thirty-one (31) of the Complaint and, therefore, denies the same.

32. The allegations contained in numbered paragraph thirty-two (32) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph thirty-two (32) of the Complaint.

33. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

34. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph thirty-four (34) of the Complaint and, therefore, denies the same.

35. The allegations contained in numbered paragraph thirty-five (35) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph thirty-five (35) of the Complaint.

36. Respondent's answers to the allegations contained in numbered paragraphs one (1) to eleven (11) of the Complaint are restated and incorporated herein by reference.

37. Respondent is without knowledge or information sufficient to form a belief as to the truth or accuracy of the allegations contained in numbered paragraph thirty-seven (37) of the Complaint and, therefore, denies the same.

38. The allegations contained in numbered paragraph thirty-eight (38) of the Complaint contain arguments and/or legal conclusions to which no response is required. To the extent that a response is required, Respondent denies the allegations contained in numbered paragraph thirty-eight (38) of the Complaint.

AFFIRMATIVE DEFENSES

Without affecting the appropriate burden of proof and otherwise without waiver, limitation, prejudice or right to amend, Respondent hereby asserts its affirmative defenses

against Complainant. Respondent reserves the right to raise additional affirmative defenses based upon further discovery and investigation.

FIRST AFFIRMATIVE DEFENSE

Respondent has not violated FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), because Agion Type AJ is the only “substance or mixture of substances” within the meaning of FIFRA § 2(u), 7 U.S.C. § 136(u), for which Respondent has made any claim that could possibly demonstrate Respondent’s pesticidal intent under 40 C.F.R. § 152.25(a), and Agion Type AJ was registered under FIFRA § 3, 7 U.S.C. § 136a, at all times relevant to this action.

SECOND AFFIRMATIVE DEFENSE

Respondent has not violated FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), because no Shoe Product is a “pesticide” within the meaning of, or for any purpose under, FIFRA or EPA’s implementing regulations.

THIRD AFFIRMATIVE DEFENSE

The Shoe Products are exempt from FIFRA regulation under 40 C.F.R. § 152.25(a).

FOURTH AFFIRMATIVE DEFENSE

Given that Complainant registered Agion Type AJ as an “end use product” within the meaning of 40 C.F.R. § 152.3, Complainant cannot logically assert that Respondent has used Agion Type AJ as a “manufacturing use product,” as defined in 40 C.F.R. § 152.3, specifically, to manufacture or formulate other pesticide products, namely, the Shoe Products, and thereby violated FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A).

FIFTH AFFIRMATIVE DEFENSE

Because Complainant has failed to adequately warn Respondent of the consequences of making “public health claims” for Shoe Products, the Complainant is estopped from alleging that Respondent has violated FIFRA § 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), by making such claims.

SIXTH AFFIRMATIVE DEFENSE

The Complaint does not comply with 40 C.F.R. § 22.14(a)(4)(ii), because Complainant has not provided a brief explanation of the severity of each violation alleged.

SEVENTH AFFIRMATIVE DEFENSE

The Complaint does not address the civil penalty determination factors required by FIFRA § 14(a)(4), 7 U.S.C. § 136l(a)(4), and is unjust in light of such factors.

EIGHTH AFFIRMATIVE DEFENSE

The Complaint does not comply with FIFRA § 14(a)(4), 7 U.S.C. § 136l(a)(4), because it does not allege significant harm from the alleged violations, and because any violations that may have occurred did so despite Respondent’s exercise of due care, which entitles Respondent to receive a warning in lieu of paying a civil penalty.

NINTH AFFIRMATIVE DEFENSE

The Complaint fails to state any violation of FIFRA.

TENTH AFFIRMATIVE DEFENSE

Complainant has no right to relief. 40 C.F.R. §§ 22.04(c)(7), 22.20(a).

ELEVENTH AFFIRMATIVE DEFENSE

The Complaint does not comply with section 553(c) of the Administrative Procedure Act, 5 U.S.C. § 553(c), because it seeks to enforce Pesticide Registration Notice 2000-1, a non-binding policy statement, as a substantive amendment to 40 C.F.R. § 152.25(a).

TWELFTH AFFIRMATIVE DEFENSE

Complainant's allegations constitute agency action that is arbitrary and capricious, and an abuse of discretion, under section 706(2)(A) of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

THIRTEENTH AFFIRMATIVE DEFENSE

Complainant does not have FIFRA jurisdiction over any insoles or footbeds for shoes that claim to control disease-causing microorganisms, because such products are regulated exclusively by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a.

REQUEST FOR HEARING

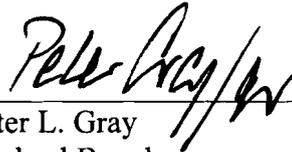
Pursuant to 40 C.F.R. § 22.15(c), Respondent requests a hearing upon the issues raised in the Complaint and herein.

WHEREFORE, Respondent prays that judgment be entered against Complainant on all claims and that the Complaint be dismissed with prejudice in its entirety.

Respectfully submitted,

This 30th day of November 2009.

BY:



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John Conner, Jr.

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Counsel for Respondent

CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2009, the original and one copy of the foregoing Answer to Complaint and Notice of Opportunity for Hearing, Affirmative Defenses, and Request for Hearing (hereinafter, "Answer") was delivered by hand to the following:

The Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 9
75 Hawthorne Street
San Francisco, California 94105

and that on November 30, 2009, a true and correct copy of the Answer also was delivered by hand to the following:

Nancy Marvel, Regional Counsel
David H. Kim, Assistant Regional Counsel
U.S. Environmental Protection Agency, Region 9
75 Hawthorne Street
San Francisco, California 94105
Counsel for Complainant



Peter L. Gray